DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Draxxin
Docket No.: 2006E-0008

SEP 11 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,420,536, filed by Pfizer, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Draxxin (tulathromycin), the animal drug product claimed by the patent.

The total length of the regulatory review period for Draxxin is 2,451 days. Of this time, 2,414 days occurred during the testing phase and 37 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: September 9, 1998.

   FDA has verified the applicant's claim that the date the investigational new animal drug application (INAD) became effective was on September 9, 1998.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: April 18, 2005.

   FDA has verified the applicant's claim that the new animal drug Application (NADA) for Draxxin (NADA 141-244) was initially submitted on April 18, 2005.

3. The date the application was approved: May 24, 2005.

   FDA has verified the applicant's claim that NADA 141-244 was approved on May 24, 2005.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas A. Wooton
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